A.P.P.A.® Project: study of pediatric formulations for using in developing Countries

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Abstract

The A.P.P.A.® Project [1] is the result of the cooperation between the Pharmacy Faculty (TO) and local Pharmacists and it is in agreement with the International Health Cooperation Principles. The Project is structured in six phases, through which it is possible to obtain an effective and functional galenic lab in hospitals located in developing Countries (DC). Due to the different socio-economic conditions each lab is a reality different from the others, always without forgetting the goal of opening labs that produce quality medicinal products. For each lab a specific handbook has been studied: for each of them reflects the different local needs. For this reason, in the last two labs carried out in Angola and Haiti, it was necessary to introduce several formulations for pediatric use. For each preparation specific tests were performed to verify the stability under different environmental conditions, in accordance with the European Medicines Agency (EMA) guidelines [2].

Achieved Results

The galenic medicines studied until now for pediatric use have been prepared in different pharmaceutical forms:

- Solutions: captopril, furosemide
- Suspensions: amoxicillin, carbocysteine, chloramphenicol, erythromycin, magnesium and aluminum hydroxide, metronidazole, vitamin B complex
- Syrups: ascorbic acid, carbocysteine, ibuprofen, iron sulphate, paracetamol, potassium canrenoate, propanolol, quinine, ranitidine, salbutamol, vitamin B6
- Drops: nifedipine, quinine, ranitidine, salbutamol, vitamin B6
- Suppositories: paracetamol

For each preparation specific tests were performed to verify the quality and also the stability under different environmental conditions, in accordance with the EMA guidelines. Up today, all formulations have proved to be stable in “Refrigerated” conditions (T=5±3°C) and “Standard” conditions (T=40±2°C, RH 60±5%) for 12 months, in “Accelerated” conditions (T=25±2°C, RH 60±5%) for 3 months.

Methodological approach

- In agreement with local medical doctors the drugs for the pediatric therapy are chosen and then formulated [6]; liquid oral formulations are preferred and appropriate excipients are selected.
- For each formulation a specific card (written in local language) has been prepared. The card shows the procedure of preparation and the characteristics of each component present in the formulation.
- Each preparation have been tested to check its quality and its stability under different environmental conditions in accordance with the EMA guidelines.

Considering the environmental conditions present in DC where the galenic products will be used and in order to investigate the stability of these medicinal products, A.P.P.A.® performed a survey of the stability of various galenic dosage forms using different environmental conditions in accordance with the EMA guidelines. We endeavoured to gather information on stability of galenics at extreme environmental conditions (high temperatures and relative humidity) that might prove useful in those Countries (e.g., African ones) where the tropical climate is a serious threat for the quality of drugs. Stability results of samples stored in “accelerated” (T=40±2°C, RH=50±5%) conditions supplied precious information on the expected stability of galenics in tropical Countries where extreme environmental conditions are often a limiting factor for correct storage of drugs.

Conclusion

- About 30 galenic medicinal products for pediatric use have been studied and then formulated.
- For all formulations quality and stability have been demonstrated in accordance with EMA guidelines.
- The studied pediatric formulations are currently in use in the A.P.P.A.® laboratories of Haiti and Angola.

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