

# Key role of Hospital Pharmacy in a Non-Profit Study involving Ruxolitinib 5 mg cps: Implementation and Quality Assurance of an Investigational Manufacturing Product

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## Background

For a no-profit study evaluating efficacy of Ruxolitinib 5 mg in patients with Hodgkin's lymphoma Investigators had to use their Research Fund able to meet only the cost of Jakavi 20 mg tablets, cheaper than the other dosages.

## Aim and Objectives

The Hospital Pharmacy aims were to improve the pharmaceutical formulation producing capsules of Ruxolitinib 5 mg starting from Jakavi 20 mg tablets

## Materials and Methods

- For each batch (200 cps) **50 tablets** of Jakavi 20 mg and **6 mg** of starch were used
- 80 samples were allocated to conduct **Uniformity of mass single-dose** preparations and stability studies
- Stability studies: three samples of 20 capsules for each one, in amber glass bottles at **storage condition (25°C – 2°C ) per 12 months** were prepared and every months by **HPLC Assay** were determined **Ruxolitinib concentration**

## Results

### Ruxolitinib used

**102 packs**  $\xrightarrow{\text{instead of}}$  **408 packs**

**Uniformity of mass studies:** no more than 2 of the individual capsules masses deviated from the average mass by more than 10% and none deviates more than twice that percentage.

### Stability Study (6 Months preliminary data)

Analyte	Theoretical Concentration (mg/ml)	Trueness(%)	Repeatability (%CV <sub>w</sub> )	Intermediate Precision (%CV <sub>p</sub> )	Tolerance Interval (%)
Ruxolitinib Phosphate	0,045	96,3	1,3	1,3	94,5-98,2
	0,12	100,3	1,1	2,9	94,4-106,3
	0,14	106,3	1,1	1,2	104,4-108,2

## Conclusions

The role of pharmacist has proved to be essential for the no profit trial implementation. Pharmacists allowed the compounding required from study design, ensuring **safety** and **quality** with a significant **cost saving**. Stability test demonstrated also that the compounding can be stored for up six months in standard conditions.